(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: 0 039 124
A1

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 81300951.1

(22) Date of filing: 06.03.81

(51) Int. Cl.³: A 61 M 5/14
A 61 F 1/00

(30) Priority: 07.03.80 US 127944

(43) Date of publication of application:
04.11.81 Bulletin 81/44

(84) Designated Contracting States:
BE CH DE FR GB IT LI NL SE

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(54) Implantable infusion apparatus.

(57) The apparatus 10 employs a collapsible infusate reservoir 14 which is biased toward its collapsed condition to supply infusate under pressure to an outlet catheter 32 via a pair of parallel flow paths 22, 34 having different fluid restriction characteristics. The flow path 34 has a controllable valve 38 and a fluid accumulator 46 is connected to the path 34 upstream of the valve 38 so that infusate can be delivered to the catheter 32 via one or both paths 22, 34 depending upon whether the valve 38 is closed or open.

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dispense a much larger dose (prolonged bolus) of insulin to offset the increased sugar level caused by the ingestion of that meal. One such programmable infusion apparatus, described in U.S. patent 4,077,405, varies the valve control pulses in frequency and/or duration to control the duty cycle of an electrically operated valve to provide the requisite basal and bolus doses at the required times.

One problem with such prior apparatus which rely on electrically operated controllers to regulate both the basal and bolus infusion rates to the patient is that they consume a relatively large amount of energy so that the energy source which is a battery must be recharged or replaced relatively often.

Prior controllable infusion apparatus is disadvantaged also in that it is possible for the patient to inadvertently or intentionally control the apparatus so as to administer an overdose of infusate. This not only exhausts the supply of infusate, but also can result in injury to the patient. An insulin overdose, for example, can bring on hypoglycemic shock resulting in death to the patient.

More generally, however, it would be desirable to provide implantable infusion apparatus which is small and compact so as to occupy a minimum amount of space in the body, yet which is able to supply the patient's basal requirements over the long term plus periodic bolus doses as needed in a controlled fashion while still avoiding the need for surgically removing the apparatus in order to refill it with infusate or to replace or recharge its power supply.

excessive glucose present in the patient's bloodstream. Accordingly we will describ the invention in that context. It should be understood, however, that the apparatus can be used to dispense a vari ty of other infusates, heparin being one example, into a human or animal body for various purposes.

The average diabetic should receive a basal dosage of insulin continuously in response to changes in the level of glucose in the bloodstream. In addition, he should receive larger, short-term, so-called bolus doses of insulin to offset much higher, short-term glucose levels in the bloodstream which may be present particularly after meals. Moreover, the bolus doses should be introduced and take effect as soon as possible and should terminate as the glucose level is returned to its basal state. The present apparatus accomplishes these objectives with a small compact package which occupies a minimum amount of space in the body and which requires a minimum amount of energy so that it can remain in the patient's body for a relatively long time.

The apparatus employs a single infusate reservoir from which both the basal and bolus infusate doses are dispensed to the infusion site in the patient's body along parallel paths having different fluid flow characteristics. Preferably, the infusate reservoir is of the type comprising a variable volume infusate chamber, e.g. a bellows capsule, which is collapsed by the pressure exerted by a confined fluid on the chamber walls to expel the infusate from the chamber. Most preferably, the fluid is a two-phase fluid which vaporizes at physiological

control signals to the valve causing it to open and close in a controlled fashion so that the requisite amount of infusate flows fr m the infusate reservoir through the second flow path to the mixing chamber where it mixes with the basal dose, the combined dose then flowing to the infusion site in the patient's body. For example, at mealtime, the patient would activate the controller. The controller would then automatically open and close the valve so that the infusion apparatus would dispense an integrated infusate dose to the patient to offset the increased glucose level in his bloodstream caused by the ingestion of that meal. That dose would be tailored to that patient's particular needs, and would cease after some predetermined time or could be terminated by the patient.

The present apparatus also limits the bolus dose volume which the apparatus can dispense within a selected time period to prevent possible injury to the patient. For example, a person may not remember that he has actuated the controller switch and received a bolus dose after a given meal and may actuate it again two or more times within a short time interval. To avoid this potential problem, the present apparatus includes an auxiliary infusate reservoir or accumulator in the second fluid path upstream from its valve. This reservoir may be similar to the main reservoir but it is quite small. Also a flow restrictor is located in the second path between the main reservoir and the auxiliary reservoir to limit infusate flow from the reservoir to the auxiliary reservoir so that the latter cannot be refilled more than once in a given time period, e.g. four to seven hours. Therefore, each time the patient actuates the controller switch

(.g. several years) before its battery requires replacement or recharging. As a result of the aforesaid advantages, the present implantable infusion apparatus should find wide application as a dispenser for insulin, hormones, drugs and other such beneficial fluids.

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description, taken in connection with the accompanying drawing, in which:

FIG. 1 is a schematic diagram of implantable infusion apparatus embodying the principles of this invention; and

FIGS. 2a to 2C are graphical diagrams of the valve function and flow rates of the FIG. 1 apparatus.

Referring to FIG. 1 of the drawing, the various apparatus components are enclosed within a housing shown in dotted lines at 10. Certain of the components are similar to the ones described in the specification of U.K.Patent Application Serial No.2,028,275A published 5th March, 1980. Accordingly, they will not be described in detail here. Suffice it to say that the housing 10 interior is subdivided into a number of fluid-tight chambers of compartments. Mounted within a relatively large chamber 12 inside the housing is a bellows capsule 14. The

Infusate from the bellows capsule 14 also flows to chamber 26 by way of a second flow path 34 which is parallel to path 22. Path 34 also has a selected flow restriction indicated at 36 which permits a faster infusate flow to chamber 26 to satisfy the patient's bolus requirement. Fluid flow along path 34 is normally blocked by a valve 38 whose operation is controlled by an electrical controller 42 activated by a switch button 42a located just under the skin. The valve may be a solenoid valve, a piezoelectric valve or other valve which responds to electrical signals. The controller is also of a conventional variety, a suitable one being described in U.S. Patent 4,077,405.

A second chamber 44 is formed in housing 10 which contains a second bellows capsule 46. Capsule 46 divides chamber 44 into two volumes, one being inside the capsule and the other being outside the capsule but within chamber 44. Fluid communication between the interior of bellows 46 and the flow path 34 upstream of valve 38 is established by a flow path 48. Also a flow restriction 52 is included in the flow path 34 between capsule 14 and capsule 46 to limit the flow rate to the latter capsule. The space inside chamber 44 but outside bellows capsule 46 is also filled with a pressurizable fluid which exerts less pressure on capsule 46 than is exerted on capsule 14. Yet that pressure still exceeds the infusion site pressure in the body. Furthermore, capsule 46 is arranged so that the amount of fluid that can be pumped from capsule 46 during a given stroke of that bellows is a small percentage of that delivered by a single stroke of capsule 14.

duration as shown in FIG. 2B. Such openings of the valve permits the capsule 46 to expel its contents as pronounced infusate slugs through the restrictor 36 to the mixing chamber 26. In that chamber, the bolus infusate flow mixes with and supplements the basal flow still arriving directly from capsule 14, with the combined or integrated infusate dosage to the patient being reflected in FIG. 2C.

Referring again to FIG. 1, the present apparatus protects the patient from inadvertent bolus infusate overdoses in the event that the valve 38 is opened repeatedly or fails in the open position. More particularly, the maximum volume of bolus infusate that is available for delivery to the patient is the contents of capsule 46. This is because the flow restrictor 52 between capsule 14 and capsule 46 is such that the capsule 46 is refilled at a slow rate, e.g. over 4 to 5 hours. Accordingly, even if the valve 38 remains open for a long time, several hours, the patient still receives only a small portion of the bolus dose of infusate.

By the same token, if the patient actuated the controller at mealtime and received a bolus dose to offset the increased blood sugar level caused by that meal and then inadvertently actuates it again a short time thereafter, he will receive only a very small amount of infusate because the capsule 46 will not have been replenished with a significant amount of infusate from 14 during that time. Thus, the provision in the present apparatus of an accumulator located between an upstream low flow rate restrictor leading from the main reservoir and a downstream valve

CLAIMS

1. Implantable infusion apparatus including a first infusate reservoir 14, a fluid outlet 28 from the apparatus, and a first flow path 22 connected between the reservoir 14 and the outlet 28, characterized in that there is provided a second flow path 34 connected between the reservoir 14 and the outlet 28, a normally closed valve 38 connected in the second flow path, a fluid accumulator 46 in fluid communication with the second flow path 34, first pressure means for exerting pressure on the reservoir 14 to expel infusat under pressure to the outlet 28, means for opening the valv 38 at selected time intervals, and means 32 for conducting the infusate from the outlet 28 to an infusion site.

2. Apparatus as claimed in claim 1 characterised in that the first and second flow paths 22, 34 have different fluid flow restriction characteristics.

3. Apparatus as claimed in claim 2 characterised in that the second flow path 34 is less restrictive than the first flow path 22.

4. Apparatus as claimed in any one of the preceding claims characterised in that the first pressure means is constituted by a fluid power cell.

wh r by the first res rvoir can be refilled with infusate by sub utaneous injection.

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EUROPEAN SEARCH REPORT

0039124
Application number
EP 81 30 0951

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
DX	US - A - 4 077 405 (HAERTEN, KRESSE) * Column 3, line 77 - column 4, line 49; column 5, line 15 - column 6, line 17; figures 1, 4-7 *	1-9
PX	US - A - 4 193 397 (TUCKER, PROSL) * Column 1, line 11 - column 2, line 13; column 4, lines 5-40; column 5, lines 52-60; column 9, lines 8-37; column 11, lines 6-64; figures 5,7 *	1-9
A	WO - A - 81/00209 (REGENTS OF THE UNIVERSITY OF MINESOTA) * Page 4, line 15 - page 6, line 25; page 8, line 27- page 9, line 4; fiugres 1,2 *	1-4,6-9

CLASSIFICATION OF THE APPLICATION (Int. Cl.³)

A 61 M 5/14
A 61 F 1/00

TECHNICAL FIELDS SEARCHED (Int. Cl.³)

A 61 F
A 61 M

CATEGORY OF CITED DOCUMENTS

X: particularly relevant
A: technological background
O: non-written disclosure
P: intermediate document
T: theory or principle underlying the invention
E: conflicting application
D: document cited in the application
L: citation for other reasons

&: member of the same patent family, corresponding document

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	24-06-1981	O'REILLY

EPO Form 1503.1 06.78